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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,079	07/08/2003	Kirk D. Swenson	44352	8339

7590 08/07/2008

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EXAMINER	
SQUIRES, ELIZA A	

ART UNIT	PAPER NUMBER
4156	

MAIL DATE	DELIVERY MODE
08/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/614,079	SWENSON ET AL.	
	Examiner	Art Unit	
	Eliza Squires	4156	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/10/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claim 8** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "said data input device" in line 2. There is insufficient antecedent basis for this limitation in the claim.

3. **Claim 22** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 recites the limitation "said data input device" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 1, 6, 9, 10, 12, 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,897,493 to *Brown* in view of “Hold the Lab in the Palm of Your Hand: Point-of-Care Blood Analyzers Speed Test Results at the Patient’s Bedside” by *McConnell.*

6. **As to claim 1,** *Brown* discloses a method of collecting and testing data from a plurality of patient point of care locations, the method comprising:

controlling a central device to receive sample data from at least one sample testing device at a patient point of care location, said sample testing device is adapted to engage an analytical device and provide said sample data, said central device adapted to maintain at least one database (see figures 1, 2, and 9, and abstract also column 1, line 6 to column 2, line 6);

controlling said central device to update said database based upon at least one of said received sample data, analytical device and patient identifier information, and provide said database to a network server (column 9 lines 66-67 and column 10 lines 1-7 and figure 1).

While *Brown* discloses the use of an analytical device connected to the remote apparatus he does not specifically state that the device is a sample cartridge, *McConnell* discloses a sample cartridge (page 57, 2nd column).

Brown also does not explicitly disclose receiving cartridge identifier information or tagging data with patient identifier information.

McConnell discloses controlling said central device to receive cartridge identifier information from said sample testing device(page 59, lower half, 2nd bullet); and

controlling said central device to tag said received sample data with a patient identifier label information, said patient identifier label information communicated to said central device via a data input device (page 58, lower half, 4th bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to expedite the collection of sample analysis results utilizing a remote system in a patient point of care system.

7. **As to claim 6,** see the discussion of claim 1. *Brown* further discloses a method of collecting and testing data from a plurality of patient point of care locations, further comprising:

controlling said central device to communicate data to said patient identifier information label as at least one data packet communicated from said central device via a second wireless communication module (figures 1 and 9).

8. **As to claim 9,** see the discussion of claim 1, however *Brown* does not explicitly disclose that the input is incorporated with the sample testing device. *McConnell* discloses, a method of collecting and testing data from a plurality of patient point of care locations, wherein said data input device is incorporated with said sample testing device (page 58, bottom half 4th bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to save time and reduce errors in identifying patient information within a point of care device.

9. **As to claim 10,** see the discussion of claim 1 however, *Brown* does not explicitly disclose that the input device is incorporated with the central device. *McConnell* discloses a method of collecting and testing data from a plurality of patient point of care locations, wherein said data input device is incorporated with said central device (page 58, bottom half 3rd bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to obtain patient records at a point of care location.

10. **With respect to claim 12,** See the discussion of claim 1; however, *Brown* does not explicitly disclose a system configuration inclusive of a contamination field. *McConnell* discloses a method of collecting and testing data from a plurality of patient point of care, wherein said testing device comprises at least one of a hand-held analytical device and stand-alone computer workstation, said testing device located within a contamination field about a patient at a patient point of care location (page 57).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to provide point of care laboratory analysis to improve efficiency and quality of patient care.

11. **With respect to claim 13,** see the discussion of claim 1, however, *Brown* does not explicitly disclose a system configuration inclusive of a contamination field. *McConnell* further discloses a method of collecting and testing data from a plurality of patient point of care locations, wherein said central device comprises at least one of a hand-held analytical device and stand-alone computer workstation, said central device located beyond a contamination field about a patient at a patient point of care location (Page 59, bottom half, 1st and 3rd bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* to provide a centralized database for a group

of such devices for increased patient privacy and improved organization of patient files for ease of use by medical personnel.

12. **Claims 2-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Brown* in view of *McConnell* in further view of U.S. Patent Application Publication 2001/0051766 to *Gazdzinski*.

13. **As to claim 2,** see the discussion of claim 1, however the prior art does not explicitly disclose utilizing a wireless network. *Gazdzinski* discloses a method of collecting and testing data from a plurality of patient point of care locations, further comprising:

controlling said sample testing device to communicate said sample data to said central device as at least one data packet communicated from said sample testing device via a first wireless communication module (see page 19 paragraph [0216] where a sample testing device is a capsule endoscope).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* in order to utilize wireless communication to transmit testing data in order to reduce cost and minimize infrastructure.

14. **As to claim 3,** see the discussion of claims 1 and 2. Additionally, *Gazdinski* further discloses a method of collecting and testing data from a plurality of patient point of care locations, further comprising:

controlling said sample testing device to communicate said sample data in a multiplexed format, said format including at least one of a time-division multiple access

(TDMA) format, code-division multiple access (CDMA) format, and frequency-division multiple access (FDMA) format (page 19 paragraph [0219]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* to utilize wireless communication including radio frequency format to obtain multiple data in order to reduce cost and minimize infrastructure.

15. **As to claim 4,** see the discussion of claim 1 above. Additionally Gazdzinski further discloses a method of collecting and testing data from a plurality of patient point of care locations, further comprising:

controlling said central device to receive said sample data from a plurality of sample testing devices simultaneously via a second wireless communication module (page 19 paragraph [0216]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* in order to allow for multiple patients to be sampled at one time saving time and expediting treatment.

16. **As to claim 5,** see the discussion of claim 1 above. Additionally, *Gazdzinski* further discloses a method of collecting and testing data from a plurality of patient point of care locations, further comprising:

controlling said central device to communicate data to said sample testing device at least one data packet communicated from said central device via a second wireless communication module (page 20 paragraph [0223]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* in order to allow two way communications between the central database and the remote device.

17. **Claims 7-8, 14-15, 20-24, 26, and 27** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Brown* in view of *McConnell* and U.S. Patent Application 2003/0140928 to *Bui et al.*

18. **As to claim 7,** see the discussion of claim 1 and 6, however the prior art does not explicitly disclose a radio frequency identifier label. *Bui* discloses a method of collecting and testing data from a plurality of patient point of care locations, wherein said patient identifier information label is a radio frequency identification label (page 2 paragraph [0022]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add increased privacy protection and reduce medical errors in the processing of test samples.

19. **As to claim 8,** see the discussion of claim 1. Additionally, *Bui* discloses a method of collecting and testing data from a plurality of patient point of care locations, wherein said data input device is at least one of a bar code reader and a radio frequency identification label (page 3 and 4, paragraph [0031]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add

increased privacy protection and reduce medical errors in the processing of test samples.

20. **As to claim 14,** *Brown* discloses a system, adapted to collect and test data at a patient point of care location from a point located beyond a contamination radius about a patient using modular components to create a point of care network, the system comprising:

an analytical device, adapted to engage a sample testing device for testing a collected sample at a patient point of care location, said sample cartridge including a cartridge identifier mechanism, adapted to provide cartridge identifier information (see figures 1, 2, and 9, abstract, and column 5 lines 35-39);

a central device, adapted to receive sample data from said sample testing device at a patient point of care location, said central device being further adapted to maintain at least one database and to update said database based upon at least one of said cartridge identifier information, patient identifier information, and received sample data, and to provide said database to a network server (column 9 lines 66-67 and column 10 lines 1-7 and figure 1).

While *Brown* discloses the use of a monitoring device connected to the remote apparatus he does not specifically state that the device is a sample cartridge, *McConnell* discloses a sample cartridge (page 57, 2nd column).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to expedite the collection of sample analysis utilizing a remote system in a medical environment.

Brown also does not explicitly disclose a patient identifier label. *Bui* discloses a patient identifier label, adapted to provide patient identifier information (paragraph [022])

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add increased privacy protection and reduce medical errors in the processing of test samples.

21. **As to claim 15,** see the discussion of claim 14, however, *Brown* does not explicitly disclose a patient identifier label. *Bui* further discloses a system wherein:

said central device is further adapted to tag said received sample data with said patient identifier label information (paragraph [022]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add increased privacy protection and reduce medical errors in the processing of test samples.

22. **As to claim 20,** see the discussion of claim 14, However, *Brown* does not explicitly disclose a patient identifier label or its use. *Bui* discloses a system wherein said central device is adapted to communicate data to said patient identifier information label as at least one data packet communicated from said central device via a second wireless communication module (paragraph [022]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add

increased privacy protection and reduce medical errors in the processing of test samples.

23. **With respect to claim 21,** see the discussion of claim 14, however prior art does not explicitly disclose a radio frequency identification label. *Bui* discloses a system wherein said patient identifier information label is a radio frequency identification label (page 2 paragraph [0022]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add increased privacy protection and reduce medical errors in the processing of test samples.

24. **With respect to claim 22,** see the discussion of claim 14. Additionally, *Bui* further discloses a system, wherein said data input device is at least one of a bar code reader and a radio frequency identification label (page 3 and 4 paragraph [0031]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Bui* in order to utilize encoded forms of data to add increased privacy protection and reduce medical errors in the processing of test samples.

25. **With respect to claim 23,** see the discussion of claim 14, however, *Brown* does not explicitly disclose that the input device is incorporated with the sample testing device. *McConnell* discloses a system, wherein said data input device is incorporated with said sample testing device (page 58, bottom half 4th bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to save time and reduce errors in identifying patient information within a point of care device.

26. **As to claim 24,** see the discussion of claim 14, however, *Brown* does not explicitly disclose that the data input device is incorporated with the sample testing device. *McConnell* further discloses a system, wherein said data input device is incorporated with said sample testing device (page 58, bottom half 3rd bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to obtain patient records at a point of care location.

27. **As to claim 26,** see the discussion of claim 14, however, *Brown* does not explicitly disclose a system configuration inclusive of a contamination field. *McConnell* discloses a system, wherein said testing device comprises at least one of a hand-held analytical device and stand-alone computer workstation, said testing device located within a contamination field about a patient at a patient point of care location (page 57).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* in order to provide point of care laboratory analysis to improve efficiency and quality of patient care.

28. **With respect to claim 27,** see the discussion of claim 14, however, *Brown* does not explicitly disclose a system configuration inclusive of a contamination field. *McConnell* discloses a system, wherein said central device comprises at least one of a hand-held analytical device and stand-alone computer workstation, said central device

located beyond a contamination field about a patient at a patient point of care location (Page 59, bottom half, 1st bullet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *McConnell* to provide a centralized database for a group of such devices for increased patient privacy and improved organization of patient files for ease of use by medical personnel.

29. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Brown* in view of *McConnell* in further view of the *I-Stat* website retrieved for the date 4/2/2003 via site http://web.archive.org/web/20030402092614/www.istat.com/products/.

30. **As to claim 11,** see the discussion of claim 1, however prior art does not explicitly disclose the type of blood tests to be performed. *I-Stat* discloses
A method of collecting and testing data from a plurality of patient point of care locations, wherein said sample data comprises pH, pCO2, pO2, pC1, pNO3, Na+, Ca++, K+, hematocrit and glucose levels in said sample (page 1 and 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *I-Stat* in order to provide a multiplicity of blood sample tests to be conducted at once in order to further expedite and improve patient treatment.

31. **Claim 25** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Brown* in view of *McConnell, Bui,* and *I-Stat.*

32. **As to claim 25,** see the discussion of claim 14, however prior art does not specifically disclose what blood tests are to be preformed. *I-Stat* discloses a system,

wherein said sample data comprises pH, pCO2, pO2, pC1, pNO3, Na+, Ca++, K+, hematocrit and glucose levels in said sample (page 1 and 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *I-Stat* in order to provide a multiplicity of blood sample tests to be conducted at once in order to further expedite and improve patient treatment.

32. **Claims 16-19,** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Brown* in view of *McConnell*, *Bui et al.,* and *Gazdzinski.*

33. **As to claim 16,** see the discussion of claim 14, however prior art does not explicitly disclose a wireless system. *Gazdzinski* discloses a system, wherein:

said sample testing device is adapted to communicate said sample data to said central device as at least one data packet communicated from said sample testing device via a first wireless communication module (see page 19 paragraph [0216] where a sample testing device is a capsule endoscope).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* in order to utilize wireless communication to transmit testing data in order to reduce cost and minimize infrastructure.

34. **As to claim 17,** see the discussion of claim 14 and 15. Additionally, *Gazdzinski* further discloses a system, wherein:

said sample testing device is adapted to communicate said sample data in a multiplexed format, said format including at least one of a time-division multiple access (TDMA) format, code-division multiple access (CDMA) format, and frequency-division multiple access (FDMA) format (page 19 paragraph [0219]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* to utilize wireless communication including radio frequency format to obtain multiple data in order to reduce cost and minimize infrastructure.

35. **As to claim 18,** see the discussion of claim 14. Additionally, *Gazdzinski* further discloses a system, wherein:

said central device is adapted to receive said sample data from a plurality of sample testing devices simultaneously via a second wireless communication module (page 19 paragraph [0216]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* in order to allow for multiple patients to be sampled at one time saving time and expediting treatment.

36. **As to claim 19,** see the discussion of claim 14. Additionally, *Gazdzinski* discloses a system, wherein said central device is adapted to communicate data to said sample testing device as at least one data packet communicated from said central device via a second wireless communication module (page 20 paragraph [0223]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Brown* with *Gazdzinski* in order to allow two way communications between the central database and the remote device

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliza Squires whose telephone number is (571)270-

7052. The examiner can normally be reached on Monday through Friday 8 am - 4 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Kyle can be reached on 571-272-6746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eliza Squires/
Examiner, Art Unit 4156
7/29/2008

/Charles R. Kyle/
Supervisory Patent Examiner, Art Unit 4156